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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,545	08/19/2003	Kinya Kobayashi	83394.0012	4285

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EXAMINER

LE, JOHN H

ART UNIT	PAPER NUMBER
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2863

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,545

Applicant(s)

KOBAYASHI ET AL.

Examiner

John H Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15, 16, 18 and 20 is/are rejected.
- 7) ☒ Claim(s) 12, 17 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/10/04&08/19/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because of the form and legal phraseology often used in patent claims, such as "means" (line 3, line 4, line 5, line 6, line 8, and line 10) should be avoided.
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not disclose or suggest "a selection means which provides a calculation value of mass spectrometry for a Mth candidate, where M is less than or equal to N, and makes a comparison between a measured value of mass spectrometry for a Mth dissociated ion entered through the second input means and the calculation value, repeating from M equal to 1 to M equal to L, where L is equal to or greater than 2 and less than or equal to N, so that a (M+1)th candidate for the structure of ion can be selected" as cited in claim 14 of the application.

Claim Objections

4. Claim 11 is objected to because of the following informalities:
Claim 11, line 3, after "amino acid", insert --,--.
Appropriate correction is required.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a first input means, a second input means, a first data, a second data, a third data, a fourth data, a first storing means, and a second storing means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to under 37 CFR 1.83(a) because they fail to show a first input means, a second input means, a first data, a second data, a third data, a

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fourth data, a first storing means, and a second storing means as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-11, 13, 15-16, 18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kobayashi et al. (USP 6,745,134).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1, 16, 18, and 20, Kobayashi et al. disclose an apparatus and computer program for analyzing mass spectrometric data (Col.3, lines 41-45) comprising: a first input means (control unit 14, Fig.1) for entering first data of an ion to be analyzed measured by mass spectrometry (Col.3, lines 45-58, Col.4, lines 32-34); a second input means (control unit 14) for entering second data of a dissociated ion of the ion measured by mass spectrometry (Col.3, lines 45-58, Col.4, lines 32-34); a first data storing means (MS data) for storing third data of mass spectrometry of a plurality of candidates for the structure of ion (Col.5, lines 3-7); a calculation means for producing fourth data of mass spectrometry of dissociated ions to be used in analyzing the plurality of candidates (Col.5, lines 17-26, Col. 6, lines 1-12, Col.11, lines 9-12, lines 43-49); and an evaluation means for evaluating the plurality of candidates (Col.6, line 63-Col.7, line 10) by making comparisons between the first and third data and between the

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second and fourth data, so that the structure of ion can be identified (Col.6, lines 30-43, Col.7, lines 11-22, Col.10, lines 30-35, Col.11, lines 12-15, lines 30-33).

Regarding claim 2, Kobayashi et al. disclose the first, second, third and fourth data include mass-to-charge ratios and ion intensities, respectively (Figs.3a, 3b, 12.a, 12.b, Col.4, lines 32-44, Col.6, lines 9-12)

Regarding claim 3, Kobayashi et al. disclose the calculation means executes a molecular orbital calculation for each candidate so that the fourth data can be obtained by calculation (Col.5, lines 17-26).

Regarding claim 4, Kobayashi et al. disclose the evaluation means comprises a selection means for selecting a candidate for the structure of ion by comparing the first and third data, the calculation means is able to calculate mass spectrometric data for a dissociated ion of the candidate selected by the selection means (Col.13, lines 43-60) and the evaluation means evaluates the candidate by comparing the first data and the mass spectrometric data calculated for the candidate by the calculation means (Col.7, lines 11-20).

Regarding claim 5, Kobayashi et al. disclose the candidates evaluated by the evaluation means are displayed with ranking (Col.7, lines 16-22).

Regarding claim 6, Kobayashi et al. disclose the calculation means calculates three-dimensional structure for each candidate (Col.12, lines 16-43).

Regarding claim 7, Kobayashi et al. disclose the calculation means provides the three-dimensional structure (Col.13, lines 7-19) by molecular dynamic calculation (Col.11, lines 34-40).

Regarding claim 8, Kobayashi et al. disclose a displaying means for displaying the three dimensional structure (Col.13, lines 7-19).

Regarding claim 9, Kobayashi et al. disclose a second data storing means (MS data) for storing the fourth data (Fig.2).

Regarding claim 10, Kobayashi et al. disclose the first data enters the first input means, the second data enters the second input means and the fourth data is calculated by the calculation means (Figs.3a, 3b, 12.a, 12.b, Col.4, lines 32-44, Col.6, lines 9-12), and wherein the apparatus estimates the structure of ion by making comparisons between the first data and the third data stored in a database, and between the second and fourth data (Col.6, lines 30-43, Col.7, lines 11-22, Col.10, lines 30-35, Col.11, lines 12-15, lines 30-33).

Regarding claim 11, Kobayashi et al. disclose the apparatus is able to execute analysis for protein and peptide having amino acid as well as protein, peptide (Col.4, lines 49-54) and sugar chain (saccharides) having modified amino acid (Col.12, lines 24-26, Col.13, lines 23-27).

Regarding claim 13, Kobayashi et al. disclose the apparatus further comprises one of an ion trap unit (Col.14, lines 19-37, lines 47-51), a triple quad time-of-flight instrument (Col.14, lines 47-56) and a tandem mass spectrometry instrument (Col.16, lines 18-24).

Regarding claim 15, Kobayashi et al. disclose an apparatus for analyzing mass spectrometric data comprising: an input means (control unit 14, Fig.1) for entering one of first data measured by mass spectrometry for an ion to be analyzed (Col.3, lines 45-

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58, Col.4, lines 32-34) and second data measured by mass spectrometry for a dissociated ion of the ion (Col.3, lines 45-58, Col.4, lines 32-34); first public data (44) of mass spectrometry for candidates for the structure of ion accessible by internet 43 (Col.12, line 62-Col.13, line 6); and second public data (44) of mass spectrometry for the structure of dissociated ion for each candidate accessible by internet 43 (Col.13, lines 28-41, Col.1, lines 54-63), wherein the apparatus evaluates the candidates by making one of comparisons between the first data and first public data and between the second data and second public data, so that the structure of ion can be identified (Col.14, lines 42-60).

Allowable Subject Matter

9. Claim14 is allowed.

10. Claims 12, 17, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

In combination with other limitations of the claims, the cited prior arts fails to teach the method is able to distinguish leucine from isoleucine which have amino acids of the same mass, as recited in (amended) claim(s) 12, 17, and 19.

In combination with other limitations of the claims, the cited prior arts fails to teach a second selection means which provides a calculation value of mass spectrometry for a Mth candidate, where M is less than or equal to N, and makes a

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comparison between a measured value of mass spectrometry for a Mth dissociated ion entered through the second input means and the calculation value, repeating from M equal to 1 to M equal to L, where L is equal to or greater than 2 and less than or equal to N, so that a (M+1)th candidate for the structure of ion can be selected, as recited in (amended) claim(s) 14.

Other Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Crooke et al. (USP 6,656,690) disclose a method to determine the structure of biomolecular targets such as nucleic acids using mass spectrometry. The methods can be used for the rapid screening of large collections of compounds. The method is capable of separating different noncovalent complexes, using techniques such as selective ion trapping, or accumulation and analyzing each complex for the structure and identity of the bound ligand using collisionally activated dissociation or MSⁿ experiments.

Sepetov et al. (USP 5,470,753) disclose a method for determining the amino acid composition, and more preferably the sequence, of a peptide using mass spectrometric techniques. The method is particularly useful for sequencing peptides isolated from natural sources or from libraries of peptides that have been prepared synthetically, and for peptides that are not amenable to Edman degradation sequencing.

Contact Information

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John H Le whose telephone number is 571-272-2275.

The examiner can normally be reached on 8:00 - 4:30.

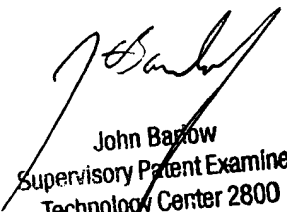
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E Barlow can be reached on 571-272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John H. Le

Patent Examiner-Group 2863

September 15, 2004


John Barlow
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